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MCDERMOTT, WILL & EMERY

August 16, 2002

VIA HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 20852

Re: Star Scientific, Inc.'s Filing of Response to Comments
Concerning Citizen Petitions, Docket Nos. 01P-0572 and 02P-0075

Dear Sir/Madam:

On behalf of our client, Star Scientific, Inc. attached please find the response to comments filed by Ropes & Gray on behalf of GlaxoSmithKline Consumer Health Care LP, on the Citizen Petitions referenced above filed concerning Star Scientific's compressed powdered hard tobacco product, Ariva™ Cigalett™ pieces.

Ariva™ is a compressed form of Star Scientific's Stonewall™ dry snuff and both products are used for tobacco satisfaction, manufactured under a license from the Bureau of Alcohol, Tobacco and Firearms, taxed as a "snuff" under federal excise laws, and subject to the warning requirements of the Comprehensive Smokeless Tobacco Health Education Act of 1986. Ariva™ is not a "food" within the meaning of the Federal Food, Drug and Cosmetic Act.

We maintain the firm belief that Star Scientific's compressed powdered hard tobacco product Ariva™ falls outside of FDA's jurisdiction, pursuant to the Supreme Court decision in *FDA v. Brown & Williamson Tobacco Corporation*, 529 U.S. 120 (2000), and that the Petitions are without merit and should be denied.

Sincerely yours,



David L. Rosen

00P-0572

RC 4

cc: Alex Azar, Esq.
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Department of Health and Human Services

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Paul L. Perito, Esq.
Chairman, President and COO
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